EFFICACY & SCIENCE SUPPORT BRANCH

ANTIMICROBIALS DIVISION

Date In: 12-12-98 Date Out 02-04-99

Reviewed by: Bruce H. Mann Microbiologist

EPA Received Date: 11-12-98

ESSB Received Data: 11-27-98

Lan Code:

EPA Reg. No. or File Symbol 1677-ROG

Product Name Advacare

Product Type Laundry Sanitizer and Sour

Company Name Ecolab., Inc.,

MRID No (s): Data were submitted under #446918-01

PM Team /Reviewer : PM-33 Swindell/Kish

Submission purpose: A new application for registration. The subject product Advacare (EPA Reg. No. 1677-ROG) is reported to be substantially similar to another registered product for the same company which is listed as Oxy-15 (EPA Reg. No. 1677-164).

The current submission is currently being proposed as a laundry sanitizer and sour (laundry additive as per DIS/TSS-13 enclosure).

Refer to attachment #1 for a description of test materials, test samples, methodology, operating procedures, generated data reports, test systems, efficacy results and control results.

Active Ingredient	%
Peroxyacetic acid	15.00
Hydrogen peroxide	11.00

202.0 Recommendations

202.0 Claims Related to Human Health

202.1 Efficacy Supported by the Submitted Data

The submitted microbiological data developed as per Subdivision G of the Product Performance Guidelines (DIS/TSS-13 enclosure(04-04-80) demonstrated adequate effectiveness as a laundry additive sanitizer aganist the microorganisms listed below. The treated samples showed a 99.9% reduction over the control counts for fabric water and laundry water for three (3) different test batches for a 5 minute exposure time against all of the indicated test microorganisms.

Product effectiveness showed satisfactory performance at the use dilution when the product was tested at a lower certified limit of 50 ppm of peroxyacetic acid in sterile distilled water, buffered with 30 ppm of 50% NaOH and 100 ppm of Sodium Bicarbonate.

As a laundry sanitizer, the product effective use dilution of 3 ounces per 100 lbs of dry weight fabric is adequate and acceptable for a 5 minute exposure time.

Effectiveness was demonstrated against the following microorganisms:

Klebsiella pneumoniae ATCC 4352,
Staphylococcus aureus ATCC 6538,
Staphylococcus aureus ATCC 33592
(Methicillin-resistant),
Pseudomonas aeruginosa ATCC 15442.

203.0 Labeling comments
Under the directions for use, after the phrase per 100 Pounds dry laundry, add "in the final rinse water".

DIS/TSS-13, April 4, 1980

EFFICACY DATA AND LABELING REQUIREMENTS

Laundry Additives - Disinfection and Sanitization

The following requirements apply to antimicrobial products which bear label claims or recommendations for use in the treatment of laundry to provide disinfecting or sanitizing activity for fabrics and/or laundry water. Label claims must distinguish between products recommended as soaking treatments prior to laundering and products represented as additives in actual laundry operations.

(a) Pre-soaking treatments. Products recommended for pre-soaking soiled fabrics prior to routine laundering must be shown to be effective by appropriate tests (e.g. AOAC Use Dilution Method for disinfectants; Sanitizer Test for inanimate non-food contact surfaces for sanitizers) in the presence of organic soil (e.g. 5% blood serum). The directions for use must specify rinsing of the items to remove gross filth prior to soaking, followed by complete immersion in an adequate volume of soaking solution (at least 5:1 w/w solution to fabric ratio, e.g. half a washload in a 3 - gallon pail) at the recommended use dilution for a specified contact time prior to the laundering operation.

(b) Laundry operations. A clear distinction should be made on the label between products recommended for household and coin-operated laundering and products represented as commercial-industrial-institutional laundry additives. The water to fabric ratio in home or coin-operated machines is about 10:1 (w/w), whereas in industrial laundering operations the ratio is about 5:1. The effectiveness of products may be significantly altered by these differences; thus, demonstrated e£ficacy in one system may not be able to be extrapolated to the other. In addition, directions for use of household laundering products may require different dosages for front-loading automatics (e.g. 8-10 gallon water capacity) and top-loading automatics and wringer-type washers (e.g. 12-15 gallon water capacity). Product dosages, in this instance, should be specified in household measurements. Dosage instructions for industrial laundering may be based on pounds of dry fabric.

The directions for use of laundry additives should specify the machine cycle in which the product is to be added, water level, temperature range, and treatment time. Compatibility of the treatment with other common laundry additives (e.g. soaps, detergents, bleach, starch, bluing, sours, fabric softeners) should be determined in testing and addressed in labeling, when applicable.

Efficacy data requirements for disinfectants and sanitizers intended for use as additives in laundry operations are as follows:

(1) Disinfection. (i) Test standard. A proposed simulated use procedure employed by Petrocci and Clarke (Petrocci, A. M. and Clarke, P. 1969. Proposed Test Method for Antimicrobial Laundry Additives. J.A.O.A.C. 52: 836-42) is acceptable. Alternately, a simulated-use study utilizing washing machines may be employed. The following basic elements must be incorporated in either study:

(A) The test bacteria are Staphylococcus aureus(ATCC 6538) and Klebsiella pneumoniae(ATCC 4352). If the product is intended for use on hospital linens, it must also be tested against Pseudomonas aeruginosa(ATCC 15442).

(B) The basic bacteriological procedures must be the same as those specified in the Petrocci and Clarke protocol.

(C) Tests must be conducted with 3 product samples, representing 3 different batches, one of which is at least 60 days old. Each sample must be tested with 9 fabric swatches against each of the specified test bacteria.

(D) The method employed must be designed to include testing both the fabric and the laundry water (5ml from the automatic washer, or 0.5 ml from the simulated washing device in individual widemouth jars containing subculture media and neutralizers. The laundry water-to-media volume ratio must not exceed 1:40.

(E) Growth or no-growth must be recorded and reported after a 48-hour incubation period.

(ii) Performance standard. There must be no growth in the fabric subcultures and no growth in the subcultures from the laundry water with all test bacteria.

(2) Sanitization. (i) Test Standard. The same type of studies referred to under "Disinfection" above must be employed for evaluating the efficacy of laundry additives intended to sanitize laundry, with the following exceptions:

(A) Tests must be conducted with 3 samples representing 3 product batches, one of which is at least 60 days old. Each sample must be

tested with 3 cloth swatches against each test microorganism required.

(B) Quantitative bacteriological assays must be conducted and the results reported.

(ii) Performance standard. At least 99.9% reduction in bacteria over the control count for both laundry water and fabric must be demonstrated against each test microorganism.

The data requirements outlined herein do not apply to sodium-calcium hypochlorites, sodium-potassium dichloro-s-triazinetriones or trichloro-s-triazinetrione.

Attachment #1

TEST SUBSTANCE/TEST SYSTEM/TEST METHOD REQUIREMENTS

To demonstrate the effectiveness of an antimicrobial product for fabric and laundry water, tests were conducted with 3 samples representing 3 different product batches, one of which was at least 60 days old. Each sample was tested with 3 fabric swatches against each of the test bacteria. The study included testing both the fabric and laundry water demonstrating at least 99.9% reduction of the test organism. (USEPA DIS/TSS-13, April 4, 1980).

TEST SYSTEM PROPAGATION

Test System Receipt

Test System Name	Date Received	Date Opened	Subculture Medium	Incubation	Date of Storage at -80°C
Klebsiella pneumoniae ATCC 4352	6/23/98	7/16/98	AOAC Nutrient broth	37 ± 2°C Aerobically for 48 hours	7/31/98
Staphylococcus aureus ATCC 6538	6/23/98	7/16/98	AOAC Nutrient broth	37 ± 2°C Aerobically for 48 hours	7/31/98
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	9/25/98	9/25/98	AOAC Nutrient broth	37 ± 2°C Aerobically for 48 hours	10/6/98
Pseudomonas aeruginosa ATCC 15442	6/23/98	7/16/98	AOAC Nutrient broth	37 ± 2°C Aerobically for 48 hours	7/31/98

Test System Identification

Test System Name	Date Removed from -80°C	Date Inoculated for Identification	Subculture Medium*	Incubation of Both Subcultures	Purity Check	Gram Stain Result	Identification
Klebsiella pneumoniae ATCC 4352	9/11/98	9/11/98	AOAC Nutrient Broth	37°C ± 2°C for 24 hours aerobically	pure	Gram negative bacilli	*Klebsiella pneumoniae*
Staphylococcus aureus ATCC 6538	9/11/98	9/14/98	AOAC Nutrient Broth	37°C ± 2°C for 24 hours aerobically	pure	Gram positive cocci	*Staphylococcus aureus*
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Culture Rec'd 9/25/98	9/27/98	AOAC Nutrient Broth	37°C ± 2°C for 24 hours aerobically	pure	Gram positive cocci	*Staphylocccus aureus*
Pseudomonas aeruginosa ATCC 15442	9/09/98	9/11/98	AOAC Nutrient Broth	37°C ± 2°C for 24 hours aerobically	pure	Gram negative bacilli	*Pseudomonas aeruginosa*

*Second subculture medium: Blood agar Lot Number 5958 for *K. pneumoniae, S. aureus* and *P. aeruginosa.*
Blood agar Lot Number 5967 for Methicillin-resistant *S. aureus.*

Test System Dates of Consecutive Transfers

Test System Name	Date/Time 1st Consecutive Transfer	Date/Time 2nd Consecutive Transfer	Date/Time 3rd Consecutive Transfer	Date/Time 4th Consecutive Transfer	Date/Time 5th Consecutive Transfer	Date/Time 6th Consecutive Transfer	Date/Time 7th Consecutive Transfer	Subculture Medium
Klebsiella pneumoniae ATCC 4352	9/12/98; 7:50 a.m. to 9/14/98; 10:50 a.m.	9/14/98; 11:04 a.m. to 9/15/98; 11:00 a.m.	9/15/98; 12:41 p.m. to 9/16/98; 10:59 a.m.	N/A	N/A	N/A	N/A	Nutrient Agar A
Staphylococcus aureus ATCC 6538	9/12/98; 7:50 a.m. to 9/14/98; 10:50 a.m.	9/14/98; 11:04 a.m. to 9/15/98; 11:00 a.m.	9/15/98; 12:41 p.m. to 9/16/98; 12:36 p.m.	9/16/98; 1:46 p.m. to 9/17/98; 1:45 p.m.	9/17/98; 2:20 p.m. to 9/18/98; 2:16 p.m.	9/18/98; 2:46 p.m. to 9/19/98; 2:00 p.m.	9/19/98; 2:00 p.m. to 9/21/98; 10:58 a.m.	Nutrient Agar A
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	9/26/98; 8:45 a.m. to 9/27/98; 11:30 a.m.	9/27/98; 11:40 a.m. to 9/28/98; 11:12 a.m.	9/28/98; 11:15 a.m. to 9/29/98; 9:34 a.m.	N/A	N/A	N/A	N/A	Nutrient Agar A
Pseudomonas aeruginosa ATCC 15442	9/10/98; 10:30 a.m. to 9/11/98; 7:50 a.m.	9/11/98; 7:54 a.m. to 9/12/98 7:45 a.m.	9/12/98; 7:50 a.m. to 9/14/98; 10:50 a.m.	9/14/98; 11:04 a.m. to 9/15/98; 11:00 a.m.	9/15/98; 12:41 p.m. to 9/16/98; 10:59 a.m.	N/A	N/A	Nutrient Agar A

TEMPERATURE RANGES OF CONSECUTIVE TRANSFERS

Test System	Temp. Range of 1st Consecutive Transfer	Temp. Range of 2nd Consecutive Transfer	Temp. Range of 3rd Consecutive Transfer	Temp. Range of 4th Consecutive Transfer	Temp. Range of 5th Consecutive Transfer	Temp. Range of 6th Consecutive Transfer	Temp. Range of 7th Consecutive Transfer	Temp. Range of Test System
Klebsiella pneumoniae ATCC 4352	36.7 - 37.2°C	36.9 - 38.1°C	37.3 - 38.0°C	N/A	N/A	N/A	N/A	36.7 - 38.1°C
Staphylococcus aureus ATCC 6538	36.7 - 37.2°C	36.9 - 38.1°C	37.0 - 37.9°C	36.3 - 37.5°C	36.3 - 36.9°C	36.2 - 36.5°C	36.2 - 36.6°C	36.2 - 38.1°C
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	35.0 - 35.3°C	35.0 - 36.2°C	35.1 - 36.4°C	N/A	N/A	N/A	N/A	35.0 - 36.4°C
Pseudomonas aeruginosa ATCC 15442	36.8 -37.2°C	36.3 - 36.8°C	36.7 - 37.2°C	36.9 - 38.1°C	37.3 - 38.0°C	N/A	N/A	36.3 - 38.1°C

French Slant Inoculation and Incubation

Test System	Date/Time/Temp. French Slants In Incubator	Date/Time/Temp. French Slants out of Incubator	Incubator # / Incubation Temperature Range	Date/Time French Slants Harvested
Klebsiella pneumoniae ATCC 4352	9/16/98, 11:14 a.m. 37.7°C	9/17/98 9:35 a.m. 36.5°C	#1 / 36.5 - 37.7°C	9/17/98, 9:41 a.m.
Staphylococcus aureus ATCC 6538	9/21/98, 11:22 a.m. 35.8°C	9/22/98, 7:56 a.m. 36.6°C	#1 / 35.8 - 36.6°C	9/22/98, 7:58 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	9/29/98, 11:07 a.m. 35.3°C	9/30/98, 7:59 a.m. 35.8°C	#1 / 35.3 - 36.4°C	9/30/98, 8:05 a.m.
Pseudomonas aeruginosa ATCC 15442	9/16/98, 11:14 a.m. 37.7°C	9/17/98, 9:35 a.m. 36.5°C	#1 / 36.5 - 37.7°C	9/17/98, 9:41 a.m.

Spectrophotomer Readings of Test Systems

Test System	Test Date	% Transmittance (initial)	mL PBDW Added to the Test System Suspension	%Transmittance (final)
Klebsiella pneumoniae ATCC 4352	9/17/98	0.4%	5.0 mL	0.6%
Staphylococcus aureus ATCC 6538	9/22/98	0.4%	0.0 mL	0.4%
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	9/30/98	0.2%	3.0 mL	0.3%
Pseudomonas aeruginosa ATCC 15442	9/17/98	0.2%	5.0 mL	0.4%

Diluent Preparation

Test Date	Volume of Diluent	Time/Temp. Autoclaved	Megaohms-cm of Milli-Q System	Date Performed
9/17/98	Six 1000 mL Flasks Two 500 mL Flasks	20 minutes at 121°C	17.0	9/16/98
9/22/98	Six 1000 mL Flasks Two 500 mL Flasks	20 minutes at 121°C	17.0	9/21/98
9/30/98	Six 1000 mL Flasks Two 500 mL Flasks	20 minutes at 121°C	17.0	9/29/98

TEST SUBSTANCE DILUTION CALCULATIONS

The test substance dilution was based on the following equations.

$$\frac{\text{50 ppm POAA}}{\text{0.127 (nominal value)}} = \text{394 ppm Oxy-15}$$

$$\frac{\text{394 g Oxy-15}}{10^6\text{ g Water}} \times \frac{\text{5 g Water}}{\text{1 g Fabric}} \times \frac{\text{1 oz. Oxy-15}}{\text{28 g Oxy-15}} \times \frac{\text{454 g Fabric}}{\text{1 lb Fabric}} \times 100 = \frac{\text{3 oz. Oxy-15}}{\text{100 lbs Fabric}}$$

The test substance dilution was calculated using the following equation:

$$\frac{\text{15 g Fabric}}{\text{75 mL Diluent}} \times \frac{\text{3 oz. Oxy-15}}{\text{100 lbs Fabric}} \times \frac{\text{1 lb Fabric}}{\text{454 g Fabric}} \times \frac{\text{28 g Oxy-15}}{\text{1 oz. Oxy-15}} \times \frac{1}{1.114}$$

= 0.025 mL **Oxy-15**/75 mL diluent

= 0.33 mL **Oxy-15**/1L diluent

The following table shows the ppm active ingredient in the test substance use-solution when diluted using the test substance with active ingredients at the lower certified limit.

Active Ingredient	Active Ingredient LCL	Specific Gravity of Oxy-15	Study Proposed Dilution	Resulting ppm of Active Ingredient
Peroxyacetic Acid	10.5%	1.114	0.03%	50
Hydrogen Peroxide	7.5%	1.114	0.03%	25

The dilution of each test substance batch to achieve the lower certified limit of both active ingredients was based on the concentration of Peroxyacetic acid in each batch. The concentration of the test substance batches to be used to yield the lower certified limit of Peroxyacetic acid for the efficacy test were as follows:

Test Substance Batch Number	Amount of Test Substance to prepare 1:10 dilution	Amount of Diluent to prepare 1:10 Dilution	Amount of 1:10 Dilution	Amount of Diluent
JJS08059C	10.0 mL	90.0 mL	3.9 mL	996.1
JJS08059D	10.0 mL	90.0 mL	2.8 mL	997.2
Si110672	10.0 mL	90.0 mL	3.2 mL	996.8

The following calculations show the dilutions of each batch of Oxy-15 in the test substance use-solution when diluted using the test substance with the POAA at the lower certified limit (LCL) of 10.5 ppm.

$$\frac{\text{3 oz. Oxy-15}}{\text{100 lbs Fabric}} = \frac{\text{0.33 mL Oxy-15}}{\text{Liter diluent}}$$

$$\frac{\text{(0.33 mL Oxy-15)(12.7 (nominal POAA))}}{\text{Liter diluent}} = \frac{\text{(x mL Oxy-15)(10.5 (LCL POAA))}}{\text{Liter diluent}}$$

$$x = 0.40 \text{ mL Oxy-15}$$

The dilution for each test substance batch was calculated using the following calculation:

$$\frac{\text{(0.40 mL Oxy-15)(10.5\%)}}{\text{Liter diluent}} = \frac{\text{(x mL Oxy-15)(\% POAA in batch)}}{\text{Liter diluent}}$$

The resulting ppm of H_2O_2 in the use solution was calculated using the following equation (the specific gravity of Oxy-15 is 1.114):

$$\frac{(H_2O_2)\,(\%\text{dilution})}{(100)\,(100)} \times 1.114 \times 10^6 = \text{ppm } H_2O_2$$

Batch JJS08059C $x = 0.39$ mL (% dilution = 0.04%)

10 mL of Batch JJS08059C were added to 90 mL diluent to achieve a 1:10 dilution. 3.9 mL of the 1:10 dilution were added to 996.1 mL diluent to achieve use-solution. Resulting ppm of H_2O_2 = 38 ppm

Batch JJS08059D $x = 0.28$ mL (% dilution = 0.03%)

10 mL of Batch JJS08059D were added to 90 mL diluent to achieve a 1:10 dilution. 2.8 mL of the 1:10 dilution were added to 997.2 mL diluent to achieve use-solution. Resulting ppm of H_2O_2 = 37 ppm

Batch Si110672 $x = 0.32$ mL (% dilution = 0.03%)

10 mL of Batch Si110672 were added to 90 mL diluent to achieve a 1:10 dilution. 3.2 mL of the 1:10 dilution were added to 996.8 mL diluent to achieve use-solution. Resulting ppm of H_2O_2 = 33 ppm

TEST SUBSTANCE DILUTION

Test Date: 9/17/98

Test Substance Diluent Preparation:

The following substances were added to obtain 100 ppm Sodium Bicarbonate and 30 ppm 50% NaOH for use as the diluent to prepare the use solutions:

Test Substance Name	Test Substance Batch Number	Amount of Sodium Bicarbonate	Resulting ppm Sodium Bicarbonate	Amount of 50% NaOH	Resulting ppm 50% NaOH
Oxy-15	JJS08059C	0.1039 g	100 ppm	0.04 mL	30 ppm
Oxy-15	JJS08059D	0.1059 g	100 ppm	0.04 mL	30 ppm
Oxy-15	Si110672	0.1063 g	100 ppm	0.04 mL	30 ppm
Diluent	Diluent	0.1073 g	100 ppm	0.04 mL	30 ppm

Test Substance Dilution:

Test Substance Name	Test Substance Batch Number	Physical Description of Concentrate	Amount of Test Substance*	Amount of Diluent	% Test Substance	Physical Description of Use-Solution	Date/Time Prepared
Oxy-15	JJS08059C	clear liquid	3.9 mL	996.1 mL	0.04%	clear liquid	9/17/98; 1:00 p.m.
Oxy-15	JJS08059D	clear liquid	2.8 mL	997.2 mL	0.03%	clear liquid	9/17/98; 1:00 p.m.
Oxy-15	Si110672	clear liquid	3.2 mL	996.8 mL	0.03%	clear liquid	9/17/98; 11:30 a.m.

*This amount was from a 1:10 dilution of the test substance.

Test Date: 9/22/98

Test Substance Diluent Preparation:

The following substances were added to obtain 100 ppm Sodium Bicarbonate and 30 ppm 50% NaOH for use as the diluent to prepare the use solutions:

Test Substance Name	Test Substance Batch Number	Amount of Sodium Bicarbonate	Resulting ppm Sodium Bicarbonate	Amount of 50% NaOH	Resulting ppm 50% NaOH
Oxy-15	JJS08059C	0.1015 g	100 ppm	0.04 mL	30 ppm
Oxy-15	JJS08059D	0.1025 g	100 ppm	0.04 mL	30 ppm
Oxy-15	Si110672	0.1002 g	100 ppm	0.04 mL	30 ppm
Diluent	Diluent	0.1059 g	100 ppm	0.04 mL	30 ppm

Test Substance Dilution:

Test Substance Name	Test Substance Batch Number	Physical Description of Concentrate	Amount of Test Substance*	Amount of Diluent	% Test Substance	Physical Description of Use-Solution	Date/Time Prepared
Oxy-15	JJS08059C	clear liquid	3.9 mL	996.1 mL	0.04%	clear liquid	9/22/98; 9:23 a.m.
Oxy-15	JJS08059D	clear liquid	2.8 mL	997.2 mL	0.03%	clear liquid	9/22/98; 9:28 a.m.
Oxy-15	Si110672	clear liquid	3.2 mL	996.8 mL	0.03%	clear liquid	9/22/98; 9:33 a.m.

*This amount was from a 1:10 dilution of the test substance.

Test Date: 9/30/98

Test Substance Diluent Preparation:
The following substances were added to obtain 100 ppm Sodium Bicarbonate and 30 ppm 50% NaOH for use as the diluent to prepare the use solutions:

Test Substance Name	Test Substance Batch Number	Amount of Sodium Bicarbonate	Resulting ppm Sodium Bicarbonate	Amount of 50% NaOH	Resulting ppm 50% NaOH
Oxy-15	JJS08059C	0.1041 g	100 ppm	0.04 mL	30 ppm
Oxy-15	JJS08059D	0.1007 g	100 ppm	0.04 mL	30 ppm
Oxy-15	Si110672	0.1027 g	100 ppm	0.04 mL	30 ppm
Diluent	Diluent	0.1019 g	100 ppm	0.04 mL	30 ppm

Test Substance Dilution:

Test Substance Name	Test Substance Batch Number	Physical Description of Concentrate	Amount of Test Substance*	Amount of Diluent	% Test Substance	Physical Description of Use-Solution	Date/Time Prepared
Oxy-15	JJS08059C	clear liquid	3.9 mL	996.1 mL	0.04%	clear liquid	9/30/98; 9:14 a.m.
Oxy-15	JJS08059D	clear liquid	2.8 mL	997.2 mL	0.03%	clear liquid	9/22/98; 9:19 a.m.
Oxy-15	Si110672	clear liquid	3.2 mL	996.8 mL	0.03%	clear liquid	9/30/98; 9:22 a.m.

*This amount was from a 1:10 dilution of the test substance.

LAUNDEROMETER CALIBRATION

Test Date	Time Power Turned on	Time Power Turned off	Starting Time/Temp	Ending Time/Temp	rpm (1,2,3)	Averaged rpm
9/17/98	7:30 a.m.	3:15 a.m.	11:05 a.m. 95.0°F	3:00 p.m. 95.0°F	43, 43, 43	43
9/22/98	7:30 a.m.	11:35 a.m.	9:40 a.m. 94.7°F	11:30 a.m. 94.5°F	43, 43, 43	43
9/30/98	7:35 a.m.	10:40 a.m.	8:45 a.m. 94.8°F	10:38 a.m. 95.0°F	42, 43, 43	42.7

CARRIER PREPARATION

Cut fabric swatches into 1 x 1½ inch pieces and place in glass petri dishes. Autoclave at 121°C for 20 minutes. Hold at room temperature.

CARRIER INOCULATION/DRYING

Carrier Inoculation/Drying Description:

Fabric carriers were inoculated with 20 µL of test system and placed in sterile petri dishes. Carriers in the petri dish were covered and then placed in an incubator under aerobic conditions for approximately 30 minutes for drying. Upon completion of the incubation, carriers were removed from the incubator.

Test Date: 9/17/98

Test System Name	Number of Carriers	Time/Temp: Carriers in Incubator	Time/Temp: Carriers out of Incubator	Total Drying Time/Temp. Range	% RH
Pseudomonas aeruginosa ATCC 15442	2	10:22 a.m. 36.1°C	10:52 a.m. 36.3°C	30 minutes 36.1-36.9°C	26.5%
Pseudomonas aeruginosa ATCC 15442	1	11:00 a.m. 36.3 °C	11:30 a.m. 36.1 °C	30 minutes 36.1-36.9 °C	26.5%
Pseudomonas aeruginosa ATCC 15442	1	11:33 a.m. 36.2 °C	12:03 p.m. 36.1 °C	30 minutes 36.1-36.9 °C	26.5%
Pseudomonas aeruginosa ATCC 15442	2	11:58 a.m. 36.2 °C	12:28 p.m. 36.2 °C	30 minutes 36.2-36.9 °C	26.5%
Pseudomonas aeruginosa ATCC 15442	2	1:14 p.m. 36.3 °C	1:44 p.m. 36.4 °C	30 mintues 36.3-36.9 °C	26.5%
Pseudomonas aeruginosa ATCC 15442	2	1:52 p.m. 36.4 °C	2:22 p.m. 36.4 °C	30 minutes 36.4-36.9 °C	26.5%
Pseudomonas aeruginosa ATCC 15442	2	2:11 p.m. 36.4 °C	2:41 p.m. 35.6 °C	30 minutes 35.6-36.9 °C	26.5%
Klebsiella pneumoniae ATCC 4352	2	10:22 a.m. 36.1°C	10:52 a.m. 36.3°C	30 minutes 36.1-36.9°C	26.5%
Klebsiella pneumoniae ATCC 4352	1	11:00 a.m. 36.3 °C	11:30 a.m. 36.1 °C	30 minutes 36.1-36.9 °C	26.5%
Klebsiella pneumoniae ATCC 4352	1	11:33 a.m. 36.2 °C	12:03 p.m. 36.1 °C	30 minutes 36.1-36.9 °C	26.5%
Klebsiella pneumoniae ATCC 4352	2	11:58 a.m. 36.2 °C	12:28 p.m. 36.2 °C	30 minutes 36.2-36.9 °C	26.5%
Klebsiella pneumoniae ATCC 4352	2	1:14 p.m. 36.3 °C	1:44 p.m. 36.4 °C	30 mintues 36.3-36.9 °C	26.5%
Klebsiella pneumoniae ATCC 4352	2	1:52 p.m. 36.4 °C	2:22 p.m. 36.4 °C	30 minutes 36.4-36.9 °C	26.5%
Klebsiella pneumoniae ATCC 4352	2	2:11 p.m. 36.4 °C	2:41 p.m. 35.6 °C	30 minutes 35.6-36.9 °C	26.5%

Test Date: 9/22/98

Test System Name	Number of Carriers	Time/Temp: Carriers in Incubator	Time/Temp: Carriers out of Incubator	Total Drying Time/Temp. Range	% RH
Staphylococcus aureus ATCC 6538	3	9:05 a.m. 36.4°C	9:35 a.m. 36.3°C	30 minutes 36.3-36.4°C	26.4%
Staphylococcus aureus ATCC 6538	4	9:56 a.m. 36.4 °C	10:26 a.m. 36.2 °C	30 minutes 36.2-36.4 °C	26.4%
Staphylococcus aureus ATCC 6538	4	10:34 a.m. 36.1 °C	11:04 a.m. 35.6 °C	30 minutes 35.6-36.4 °C	26.4%
Staphylococcus aureus ATCC 6538	1	10:48 a.m. 36.0 °C	11:18 a.m. 35.7 °C	30 minutes 35.7-36.4 °C	26.4%

Test Date: 9/30/98

Test System Name	Number of Carriers	Time/Temp: Carriers in Incubator	Time/Temp: Carriers out of Incubator	Total Drying Time/Temp. Range	% RH
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	3	8:57 a.m. 35.8°C	9:27 a.m. 35.4°C	30 minutes 35.4-35.9°C	26.8%
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	4	9:15 a.m. 35.4 °C	9:45 a.m. 35.3 °C	30 minutes 35.3-35.9 °C	26.8%
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	4	9:38 a.m. 35.3 °C	10:08 a.m. 35.3 °C	30 minutes 35.3-35.9 °C	26.8%
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	1	9:58 a.m. 35.3 °C	10:28 a.m. 35.3 °C	30 minutes 35.3-35.9 °C	26.8%

EFFICACY TEST OPERATING PROCEDURE

Fabric swatches were placed in the fabric wound stainless steel spindle and placed in the exposure chamber. 75.0 mL of each test substance batch use-solution was dispensed into the sterile exposure chambers. The exposure chamber was secured in the launderometer and agitated for 5 minutes at 90 ± 5°F. One mL of each use solution was placed into neutralizer after the 5 minute exposure time. Test swatches were then aseptically removed from the exposure chamber, placed into 1% Sodium thiosulfate neutralizer and vortexed. Serial dilutions were performed in phosphate buffered dilution water. Pour plate technique was employed. Plates were inverted and incubated at 37±2°C for 48 hours.

The initial laundry water count was obtained by placing a dried fabric swatch into the fabric wound stainless steel spindle. This was prepared in triplicate. The fabric and spindle were placed into the exposure chamber and 75 mL sterile water was added. The exposure chamber was secured in the launderometer and run for the 5 minute exposure time. Serial dilutions in phosphate buffered dilution water were performed on the water sample after the 5 minutes exposure time. Pour plate technique was employed. Plates were inverted and incubated at the 37±2°C for 48 hours.

Dry Carrier Enumeration (Inoculation and Drying of Carriers)

Test Date: 9/17/98

Test System	Number of Carriers	Time/Temp. Carrier in Incubator	Time/Temp. Carrier out of Incubator	%RH
Pseudomonas aeruginosa ATCC 15442	3	12:37 p.m. 36.1°C	1:07 p.m. 36.4°C	*26.5%
Klebsiella pneumoniae ATCC 4352	3	12:37 p.m. 36.1°C	1:07 p.m. 36.4°C	*26.5%

*This value indicates the relative humidity of the incubator.

OPERATING PROCEDURE

Test Date: 9/17/98

Test System	Test Substance Batch Number	Time Exposure Chamber in Launderometer	Time Exposure Chamber out of Launderometer	Temp. of Use Solution or Water after Exposure Time	Time Swatch into Neutralizer	Time Use Solution or Water into Neutralizer
Pseudomonas aeruginosa ATCC 15442	Water Control 1	11:07 a.m.	11:12 a.m.	92.1°F	N/A	11:15 a.m.
Pseudomonas aeruginosa ATCC 15442	Water Control 2	11:07 a.m.	11:12 a.m.	91.9°F	N/A	11:15 a.m.
Pseudomonas aeruginosa ATCC 15442	Water Control 3	11:38 a.m.	11:43 a.m.	90.4°F	N/A	11:46 a.m.
Pseudomonas aeruginosa ATCC 15442	Si110672	12:06 p.m.	12:11 p.m.	91.5°F	12:13 p.m.	12:13 p.m.
Pseudomonas aeruginosa ATCC 15442	Si110672	12:32 p.m.	12:37 p.m.	92.2°F	12:39 p.m.	12:39 p.m.
Pseudomonas aeruginosa ATCC 15442	Si110672	12:32 p.m.	12:37 p.m.	91.9°F	12:40 p.m.	12:40 p.m.
Pseudomonas aeruginosa ATCC 15442	JJS08059C	1:49 p.m.	1:54 p.m.	92.2°F	1:56 p.m.	1:56 p.m.
Pseudomonas aeruginosa ATCC 15442	JJS08059C	1:49 p.m.	1:54 p.m.	91.2°F	1:57 p.m.	1:57 p.m.
Pseudomonas aeruginosa ATCC 15442	JJS08059C	2:26 p.m.	2:31 p.m.	92.1°F	2:32 p.m.	2:32 p.m.
Pseudomonas aeruginosa ATCC 15442	JJS08059D	2:26 p.m.	2:31 p.m.	91.5°F	2:33 p.m.	2:33 p.m.
Pseudomonas aeruginosa ATCC 15442	JJS08059D	2:45 p.m.	2:50 p.m.	92.3°F	2:52 p.m.	2:52 p.m.
Pseudomonas aeruginosa ATCC 15442	JJS08059D	2:45 p.m.	2:50 p.m.	91.9°F	2:53 p.m.	2:53 p.m.
Klebsiella pneumoniae ATCC 4352	Water Control 1	11:07 a.m.	11:12 a.m.	92.5°F	N/A	11:15 a.m.
Klebsiella pneumoniae ATCC 4352	Water Control 2	11:07 a.m.	11:12 a.m.	92.1°F	N/A	11:15 a.m.
Klebsiella pneumoniae ATCC 4352	Water Control 3	11:38 a.m.	11:43 a.m.	90.9°F	N/A	11:46 a.m.
Klebsiella pneumoniae ATCC 4352	Si110672	12:06 p.m.	12:11 p.m.	93.1°F	12:13p.m.	12:13p.m.
Klebsiella pneumoniae ATCC 4352	Si110672	12:32 p.m.	12:37 p.m.	91.5°F	12:39 p.m.	12:39 p.m.

Test System	Test Substance Batch Number	Time Exposure Chamber in Launderometer	Time Exposure Chamber out of Launderometer	Temp. of Use Solution or Water after Exposure Time	Time Swatch into Neutralizer	Time Use Solution or Water into Neutralizer*
Klebsiella pneumoniae ATCC 4352	Si110672	12:32 p.m.	12:37 p.m.	91.5°F	12:40 p.m.	12:40 p.m.
Klebsiella pneumoniae ATCC 4352	JJS08059C	1:49 p.m.	1:54 p.m.	92.3°F	1:56 p.m.	1:56 p.m.
Klebsiella pneumoniae ATCC 4352	JJS08059C	1:49 p.m.	1:54 p.m.	91.5°F	1:57 p.m.	1:57 p.m.
Klebsiella pneumoniae ATCC 4352	JJS08059C	2:26 p.m.	2:31 p.m.	93.4°F	2:32 p.m.	2:32 p.m.
Klebsiella pneumoniae ATCC 4352	JJS08059D	2:26 p.m.	2:31 p.m.	92.0°F	2:33 p.m.	2:33 p.m.
Klebsiella pneumoniae ATCC 4352	JJS08059D	2:45 p.m.	2:50 p.m.	92.5°F	2:52 p.m.	2:52 p.m.
Klebsiella pneumoniae ATCC 4352	JJS08059D	2:45 p.m.	2:50 p.m.	91.5°F	2:53 p.m.	2:53 p.m.

*Water Control was placed in 10.0 mL Phosphate Buffered Dilution Water rather than neutralizer.

Dry Carrier Enumeration (Inoculation and Drying of Carriers)

Test Date: 9/22/98

Test System	Number of Carriers	Time/Temp. Carrier in Incubator	Time/Temp. Carrier out of Incubator	%RH*
Staphylococcus aureus ATCC 6538	3	9:05 a.m. 36.4°C	9:35 a.m. 36.3°C	*26.4%

*This value indicates the relative humidity of the incubator.

OPERATING PROCEDURE

Test Date: 9/22/98

Test System	Test Substance Batch Number	Time Exposure Chamber in Launderometer	Time Exposure Chamber out of Launderometer	Temp. of Use Solution or Water after Exposure Time	Time Swatch into Neutralizer	Time Use Solution or Water into Neutralizer*
Staphylococcus aureus ATCC 6538	Water Control 1	9:43 a.m.	9:48 a.m.	93.0°F	N/A	9:51 a.m.
Staphylococcus aureus ATCC 6538	Water Control 2	9:43 a.m.	9:48 a.m.	90.8°F	N/A	9:51 a.m.
Staphylococcus aureus ATCC 6538	Water Control 3	9:43 a.m.	9:48 a.m.	90.6°F	N/A	9:51 a.m.
Staphylococcus aureus ATCC 6538	Si110672	11:07 a.m.	11:12 a.m.	94.0°F	11:13 a.m.	11:13 a.m.
Staphylococcus aureus ATCC 6538	Si110672	11:07 a.m.	11:12 a.m.	92.8°F	11:14 a.m.	11:14 a.m.
Staphylococcus aureus ATCC 6538	Si110672	11:20 a.m.	11:25 a.m.	93.9°F	11:27 a.m.	11:27 a.m.
Staphylococcus aureus ATCC 6538	JJS08059C	10:30 a.m.	10:35 a.m.	92.3°F	10:37 a.m.	10:37 a.m.

Test System	Test Substance Batch Number	Time Exposure Chamber in Launderometer	Time Exposure Chamber out of Launderometer	Temp. of Use Solution or Water after Exposure Time	Time Swatch into Neutralizer	Time Use Solution or Water into Neutralizer*
Staphylococcus aureus ATCC 6538	JJS08059C	10:30 a.m.	10:35 a.m.	92.4°F	10:38 a.m.	10:38 a.m.
Staphylococcus aureus ATCC 6538	JJS08059C	10:30 a.m.	10:35 a.m.	91.6°F	10:38 a.m.	10:38 a.m.
Staphylococcus aureus ATCC 6538	JJS08059D	10:30 a.m.	10:35 a.m.	92.8°F	10:37 a.m.	10:37 a.m.
Staphylococcus aureus ATCC 6538	JJS08059D	11:07 a.m.	11:12 a.m.	94.1°F	11:14 a.m.	11:14 a.m.
Staphylococcus aureus ATCC 6538	JJS08059D	11:07 a.m.	11:12 a.m.	92.3°F	11:14 a.m.	11:14 a.m.

*Water Control was placed in 10.0 mL Phosphate Buffered Dilution Water rather than neutralizer.

Dry Carrier Enumeration (Inoculation and Drying of Carriers)

Test Date: 9/30/98

Test System	Number of Carriers	Time/Temp. Carrier in Incubator	Time/Temp. Carrier out of Incubator	%RH
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	3	8:57 a.m. 35.8°C	9:27 a.m. 35.4°C	*26.8%

*This value indicates the relative humidity of the incubator.

OPERATING PROCEDURE

Test Date: 9/30/98

Test System	Test Substance Batch Number	Time Exposure Chamber in Launderometer	Time Exposure Chamber out of Launderometer	Temp. of Use Solution or Water after Exposure Time	Time Swatch into Neutralizer	Time Use Solution or Water into Neutralizer*
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Water Control 1	9:32 a.m.	9:37 a.m.	93.7°F	N/A	9:39 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Water Control 2	9:32 a.m.	9:37 a.m.	91.3°F	N/A	9:39 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Water Control 3	9:32 a.m.	9:37 a.m.	91.2°F	N/A	9:39 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Si110672	10:13 a.m.	10:18 a.m.	92.1°F	10:19 a.m.	10:19 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Si110672	10:13 a.m.	10:18 a.m.	93.0°F	10:20 a.m.	10:20 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Si110672	10:29 a.m.	10:34 a.m.	92.4°F	10:35 a.m.	10:35 a.m.

Test System	Test Substance Batch Number	Time Exposure Chamber in Launderometer	Time Exposure Chamber out of Launderometer	Temp. of Use Solution or Water after Exposure Time	Time Swatch into Neutralizer	Time Use Solution or Water into Neutralizer*
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	JJS08059C	9:53 a.m.	9:58 a.m.	92.1°F	9:59 a.m.	9:59 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	JJS08059C	9:53 a.m.	9:58 a.m.	92.7°F	10:00 a.m.	10:00 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	JJS08059C	9:53 a.m.	9:58 a.m.	93.0°F	10:00 a.m.	10:00 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	JJS08059D	9:53 a.m.	9:58 a.m.	93.2°F	10:00 a.m.	10:00 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	JJS08059D	10:13 a.m.	10:18 a.m.	94.2°F	10:19 a.m.	10:19 a.m.
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	JJS08059D	10:13 a.m.	10:18 a.m.	93.3°F	10:19 a.m.	10:19 a.m.

*Water Control was placed in 10.0 mL Phosphate Buffered Dilution Water rather than neutralizer.

CONTROL TESTS

1. Neutralization Method

Duplicate neutralization method checks were performed on each test system. Testing was performed as follows:

Test A = 1 mL of test substance use-solution was added to 9 mL of the neutralizer and mixed. 0.1 mL of 10^3 CFU/mL test suspension was added and mixed.

Test B = 1 mL of test substance diluent was added to 9 mL of the neutralizer and mixed. 0.1 mL of 10^3 CFU/mL test suspension was added and mixed.

Test C = 0.1 mL of 10^3 CFU/mL test suspension was added to 10 mL of the phosphate buffered dilution water and mixed.

After 30 minutes, tubes were enumerated by plating 0.1 mL and 1.0 mL using pour plate technique. Plates were incubated for 48 hours at test system specific temperature.

The inoculum was prepared as follows:

$$\sim 10^8 \text{ CFU/mL} \xrightarrow[\text{dilution}]{1:100} 10^6 \text{ CFU/mL} \xrightarrow[\text{dilution}]{1:100} 10^4 \text{ CFU/mL} \xrightarrow[\text{dilution}]{1:10} 10^3 \text{ CFU/mL}$$

Test System	Test Date	Batch Number	Start Time	End Time	Exposure Time
Pseudomonas aeruginosa ATCC 15442	9/17/98	JJS08059D	3:21 p.m.	3:51 p.m.	30 minutes
Klebsiella pneumoniae ATCC 4352	9/17/98	JJS08059D	3:21 p.m.	3:51 p.m.	30 minutes
Staphylococcus aureus ATCC 6538	9/22/98	JJS08059C	11:42 a.m.	12:12 p.m.	30 minutes
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	9/30/98	Si110672	10:44 a.m.	11:14 a.m.	30 minutes

2. Diluent Control

1.0 mL of diluent used in the test was plated. Plates were incubated at 37±2°C for 48 hours.

TEST AND CONTROLS INCUBATION

Test System	Test Date	Date/Time and Temp. in Incubator	Date/Time and Temp. Out of Incubator	Total Time/Temp Range of Incubation
Pseudomonas aeruginosa ATCC 15442	9/17/98	9/17/98; 4:45 p.m.; 36.6°C	9/19/98; 2:55 p.m.; 36.6°C*	46 hours 10 minutes 36.6-36.7°C
Klebsiella pneumoniae ATCC 4352	9/17/98	9/17/98; 4:45 p.m.; 36.6°C	9/19/98; 2:55 p.m.; 36.6°C*	46 hours 10 minutes 36.6-36.7°C
Staphylococcus aureus ATCC 6538	9/22/98	9/22/98; 12:54 p.m.; 36.5°C	9/24/98; 12:54 p.m.; 36.5°C	48 hours 36.4-36.5°C
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	9/30/98	9/30/98; 11:45 a.m.; 36.5°C	10/02/98; 11:45 a.m.; 36.5°C	48 hours 36.5-36.7°C

*Plates were taken out of the incubator at 2:55 p.m. on 9/19/98 and placed into refrigerator #18 at 2:57 p.m. at a temperature of 5.9°C until 9/21/98 at 7:36 a.m. (5.5°C) at which time results were read.

EFFICACY TEST RESULTS

Dry Carrier Inoculum Numbers

Test System	Test Date	A (CFU/mL)	B (CFU/mL)	C (CFU/mL)	Average (CFU/mL)
Pseudomonas aeruginosa ATCC 15442	9/17/98	29×10^7	20×10^7	34×10^7	2.8×10^8
Klebsiella pneumoniae ATCC 4352	9/17/98	107×10^6	136×10^6	95×10^6	1.1×10^8
Staphylococcus aureus ATCC 6538	9/22/98	52×10^6	80×10^6	84×10^6	7.2×10^7
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	9/30/98	39×10^7	31×10^7	34×10^7	3.5×10^8

Dry Carrier Enumeration Conclusions

The dry carrier enumeration numbers for *Pseudomonas aeruginosa* ATCC 15442 were an average of 2.8×10^8 CFU/mL. The dry carrier enumeration numbers for *Klebsiella pneumoniae* ATCC 4352 were an average of 1.1×10^8 CFU/mL. The dry carrier enumeration numbers for *Staphylococcus aureus* ATCC 6538 were an average of 7.2×10^7 CFU/mL. The dry carrier enumeration numbers for Methicillin-resistant *Staphylococcus aureus* ATCC 33592 were an average of 3.5×10^8 CFU/mL.

Dried Carrier after Exposure Results

Pseudomonas aeruginosa ATCC 15442
Test Date: 9/17/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, <10, <10	<10	>99.9
JJS08059C	<10, <10, <10	<10	>99.9
JJS08059D	8, 2, 5×10^1	5.0×10^1	>99.9

Dried Carrier after Exposure Results (Continued)

Klebsiella pneumoniae ATCC 4352
Test Date: 9/17/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, <10, <10	<10	>99.9
JJS08059C	68, 3, 8×10^1	2.6×10^2	>99.9
JJS08059D	<10, <10, <10	<10	>99.9

Staphylococcus aureus ATCC 6538
Test Date: 9/22/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, 4, 26×10^1	1.0×10^2	>99.9
JJS08059C	<10, <10, <10	<10	>99.9
JJS08059D	<10, <10, <10	<10	>99.9

Methicillin-resistant *Staphylococcus aureus* ATCC 33592
Test Date: 9/30/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, <10, $1x\ 10^1$	1.0×10^1	>99.9
JJS08059C	<10, <10, <10	<10	>99.9
JJS08059D	<10, <10, <10	<10	>99.9

Laundry Water Control Numbers

Test System	A (CFU/mL)	B (CFU/mL)	C (CFU/mL)	Average (CFU/mL)
Pseudomonas aeruginosa ATCC 15442	6×10^5	3×10^5	28×10^1	3.0×10^5
Klebsiella pneumoniae ATCC 4352	10×10^5	11×10^5	162×10^1	7.0×10^5
Staphylococcus aureus ATCC 6538	5×10^5	6×10^5	4×10^5	5.0×10^5
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	21×10^5	28×10^5	21×10^5	2.3×10^6

Use-Solution Test Results

Pseudomonas aeruginosa ATCC 15442
Test Date: 9/17/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, <10, 1×10^1	1.0×10^1	>99.9
JJS08059C	<10, <10, 2×10^1	1.3×10^1	>99.9
JJS08059D	<10, <10, <10	<10	>99.9

Klebsiella penumoniae ATCC 4352
Test Date: 9/17/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, <10, <10	<10	>99.9
JJS08059C	<10, <10, 1×10^1	1.0×10^1	>99.9
JJS08059D	<10, <10, <10	<10	>99.9

Staphylococcus aureus ATCC 6538
Test Date: 9/22/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, <10, <10	<10	>99.9
JJS08059C	<10, <10, <10	<10	>99.9
JJS08059D	<10, <10, 1×10^1	1×10^1	>99.9

Methicillin-resistant *Staphylococcus aureus* ATCC 33592
Test Date: 9/30/98

Test Substance Batch Number	CFU/mL Survivors	Average CFU/mL	Percent Reduction
Si110672	<10, <10, <10	<10	>99.9
JJS08059C	<10, <10, 1x 10^1	1.0 x 10^1	>99.9
JJS08059D	<10, <10, <10	<10	>99.9

Percent Reduction = $\frac{\text{(Inoculum Numbers Average CFU/mL) - (Average CFU/mL of Results)}}{\text{(Inoculum Numbers Average CFU/mL)}} \times 100$

CONTROL TEST RESULTS AND CONCLUSIONS

1. Neutralization Method Results

Test System	Test Substance Batch Number	Test	Results (CFU/mL)	Average (CFU/mL)
Pseudomonas aeruginosa ATCC 15442	JJS08059D	A	152, 164 x 10^2	1.6 x 10^4
		B	115, 163 x 10^2	1.4x 10^4
		C	120, 222 x 10^2	1.7 x 10^4
Klebsiella pneumoniae ATCC 4352	JJS08059D	A	97, 73 x 10^2	8.5 x 10^3
		B	77, 76 x 10^2	7.7 x 10^3
		C	76, 99 x 10^2	8.8 x 10^3
Staphylococcus aureus ATCC 6538	JJS08059C	A	57, 46 x 10^2	5.2 x 10^3
		B	64, 38 x 10^2	5.1 x 10^3
		C	70, 59 x 10^2	6.5 x 10^3
Methicillin-resistant *Staphylococcus aureus* ATCC 33592	Si110672	A	168, 120 x 10^2	1.4 x 10^4
		B	152, 173 x 10^2	1.6 x 10^4
		C	143, 141 x 10^2	1.4 x 10^4

2. Diluent Sterility Control Results

No growth was observed on the plates from any of the test dates.

Control Result Conclusions

The neutralizer demonstrated effective neutralization of **Oxy-15** without being detrimental to the test systems. The diluent utilized for the preparation of the test substance was found to be sterile.